K 052867

DEC 2 3 2005

Ortho-Clinical Diagnostics
a Johnson-Johnson company
100 Indigo Creek Drive
Rochester, New York 14626-5101

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4253
Contact Person: Darlene Phillips

2. **Preparation Date**

October 10, 2005

3. **Device name**

Trade or Proprietary Names:
VITROS Chemistry Products dTIBC Reagent
VITROS Chemistry Products Calibrator Kit 29
VITROS Chemistry Products Performance Verifiers I & II

Common Names:
Total iron binding capacity assay

Classification Names:
Iron-binding capacity test system (862.1415): Class: I

Calibrator (862.1150): Calibrator Kit 29: Class II.

Quality Control material (assayed and unassayed) (862.1660): Class I (general controls). Since these devices (VITROS Performance Verifiers I & II) are assayed controls, they meet the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

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4. Predicate Devices

The VITROS Chemistry Products dTIBC assay is substantially equivalent to the Dade Behring Total Iron Binding Capacity (IBCT) Flex® assay on the Dimension® clinical chemistry systems.

The VITROS Chemistry Products Performance Verifiers I and II are substantially equivalent to the VITROS Chemistry Products Performance Verifiers I and II.

5. Device description

The VITROS Chemistry Products dTIBC Reagent is used in conjunction with the VITROS Chemistry Products Calibrator Kit 29 on the VITROS 5,1 FS Chemistry Systems for the quantitative measurement of TIBC in human serum.

The VITROS Chemistry Products dTIBC Reagent is a dual chambered package containing ready-to-use liquid reagents. Reagent 1, an acidic buffer containing ferric ions bound to chromazurol B (iron-binding dye) is added to the sample. The acidic pH releases iron from transferrin and the released iron binds to the excess chromazurol B. Reagent 2, a neutral buffer is added, shifting the pH, which results in increased affinity of transferrin for iron. Serum transferrin rapidly extracts iron from the dye-iron complex. The decrease in absorbance of the colored dye-iron complex is directly proportional to the total iron-binding capacity of the sample and is measured spectrophotometrically at 660 nm. Once a calibration has been performed, the TIBC concentration in each unknown sample can be determined using the stored calibration curve and the measured absorbance obtained in the assay of the sample.

The VITROS Chemistry Products Calibrator Kit 29 is a two level standard used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of total iron binding capacity (TIBC). VITROS Calibrator Kit 29 level 1 is an aqueous solution containing processed bovine serum albumin, and preservative. VITROS Calibrator Kit 29 level 2 is a lyophilate containing processed human serum, proteins, enzymes, organic compounds, electrolytes, immunoglobulins, inorganic compounds, hormones, and metals. The VITROS Chemistry Products FS Reconstitution Diluent is processed water used to reconstitute the VITROS Calibrator Kit 29 level 2.

The VITROS Chemistry Products Performance Verifiers I and II are lyophilized materials prepared from processed human serum to which enzymes, electrolytes, stabilizers, preservatives, and other organic analytes have been added. The lypohilate is reconstituted using diluent manufactured from processed water to which inorganic salts have been added. These are assayed quality control materials are used to monitor the performance of the VITROS dTIBC assay on the VITROS 5,1 FS System.

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5. Device description *(continued)*

The VITROS dTIBC assay utilizes VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline), a common reagent that is used by multiple assays on the VITROS 5,1 FS System. This is a dual chambered package containing two ready-to-use liquid diluents. Diluent 1 (Saline) is prepared from processed water to which inorganic salt has been added. Diluent 2 (BSA) is prepared from processed water to which bovine serum albumin, inorganic salts and preservatives have been added.

The VITROS 5,1 FS Chemistry System is a clinical chemistry instrument that provides automated use of the VITROS Chemistry Products MicroTip® and MicroSlides® range of products. The VITROS 5,1 FS Chemistry System was cleared for market by a separate 510(k) premarket notification (K031924).

6. Device intended uses

VITROS Chemistry Products dTIBC Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products dTIBC Reagent is used to quantitatively measure total iron-binding capacity (TIBC) in human serum.

VITROS Chemistry Products Calibrator Kit 29: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 29 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of total iron-binding capacity (TIBC) using VITROS Chemistry Products dTIBC Reagent.

VITROS Chemistry Products Performance Verifiers I & II: For *in vitro* diagnostic use only. VITROS Chemistry Products Performance Verifiers are assayed controls used to monitor the performance of VITROS Chemistry Systems.

7. Comparison to predicate devices

The VITROS Chemistry Products dTIBC Reagent and VITROS Chemistry Products Calibrator Kit 29 are substantially equivalent to the Dade Behring Total Iron Binding Capacity (IBCT) Flex® reagent cartridge (K994115) on the Dimension® clinical chemistry systems. (K994115) and Dade Behring IBCT Calibrator (K994114) (predicate devices) which were cleared by the FDA for IVD use.

The relationship between the VITROS dTIBC assay and the predicate device, determined by least squares linear regression, is:

$$\text{VITROS dTIBC} = 0.94\ X + 12.99\ (\mu g/dL),$$

with a correlation coefficient of 0.981,
where X is the Dade Behring Total Iron Binding Capacity (IBCT) Flex® assay on the Dimension® clinical chemistry system.

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7. **Comparison to predicate devices** *(continued)*

The VITROS Chemistry Products Performance Verifiers I & II are substantially equivalent to the VITROS Chemistry Products Performance Verifiers I & II (predicate device) which was cleared by the FDA (K042006) for IVD use.

In addition to correlation studies, bench testing was performed to determine assay precision, linearity, specificity, expected values, limit of detection, dilution and specimen matrix of the VITROS dTIBC assay.

Tables 1 and 2 summarize the similarities and differences between the new devices and the predicates.

Table 1 Similarities and differences between the VITROS dTIBC assay (new device) and the DADE IBCT assay (predicate device).

Similarities	
Intended Use	For *in vitro* diagnostic use only. Used to quantitatively measure total iron-binding capacity (TIBC) in human samples. The iron binding capacity is useful in the differential diagnosis of anemia, iron deficiency anemia, thalassemia, sideroblastic anemia, and iron poisoning.
Sample Pretreatment	None required
Instrumentation	Clinical chemistry analyzer
Calibration	Traceable to NIST SRM 937

Differences		
Device Characteristic	**VITROS dTIBC assay (New device)**	**DADE IBCT assay (Predicate device)**
Sample Type	Human Serum	Human Serum and plasma
Reportable Range	60 – 650 µg/dL	0 - 1000 µg/dL
Calibrators	Two levels	Three levels

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Table 2 Similarities and differences between the VITROS Performance Verifiers (new device) and the VITROS Performance Verifiers (predicate device).

Similarities	
Matrix	The lyophilized performance verifiers are prepared from processed human serum to which enzymes, electrolytes, stabilizers, preservatives, and other organic analytes have been added.
Diluent	Manufactured from processed water to which inorganic salts have been added.
Number of levels	Two

Differences		
Device Characteristic	**VITROS Performance Verifiers (New Device)**	**VITROS Performance Verifiers (Predicate Device)**
Indications for Use	For *in vitro* diagnostic use only. Assayed controls used to monitor the performance on VITROS Chemistry Systems. New additional intended use: to monitor performance of VITROS dTIBC assay on VITROS 5,1 FS Chemistry Systems.	For *in vitro* diagnostic use only. Assayed controls used to monitor the performance on VITROS Chemistry Systems.
VITROS assays supported	VITROS dTIBC MicroTip assay in addition to all of those supported by the predicate device.	Several assays including VITROS ALB, TP, TRIG, URIC, LAC, and dHDL, and TIBC MicroSlide® assays and VITROS dHDL and dLDL MicroTip® assays.

Conclusions The data presented in the premarket notification provide a reasonable assurance that the VITROS dTIBC assay and the VITROS Chemistry Products Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices.

Equivalence to predicates was demonstrated using commercially available reagents along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 3 2005

Ms. Darlene Phillips
Regulatory Associate
Ortho-Clinical Diagnostic, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: k052867
Trade/Device Name: VITROS Chemistry Products dTIBC Regent
VITROS Chemistry Products Calibrator Kit 29
VITROS Chemistry Products Chemistry Performance Verifiers I & II
Regulation Number: 21 CFR 862.1415
Regulation Name: Iron-binding capacity test system
Regulatory Class: Class I
Product Code: JMO, JIS, JJY
Dated: October 7, 2005
Received: October 11, 2005

Dear Ms. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

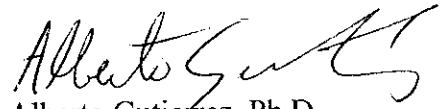
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052867

Device Name(s): VITROS Chemistry Products dTIBC Reagent
VITROS Chemistry Products Calibrator Kit 29
VITROS Chemistry Products Performance Verifiers I & II

Indications for Use: For *in vitro* diagnostic use only. VITROS Chemistry Products dTIBC Reagent is used to quantitatively measure total iron-binding capacity (TIBC) in human serum. The iron binding capacity is useful in the differential diagnosis of anemia, iron deficiency anemia, thalassemia, sideroblastic anemia, and iron poisoning.

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 29 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of total iron-binding capacity (TIBC) using VITROS Chemistry Products dTIBC Reagent.

For *in vitro* diagnostic use only. VITROS Chemistry Products Performance Verifiers are assayed controls intended for use in monitoring performance on VITROS Chemistry Systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ann Charles
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052867